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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/049,558      | 06/26/2002  | Dirk-Henning Menz    | 740-X02-007         | 7448             |

7590

11/30/2004

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EXAMINER

YOUNG, MICAH PAUL

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1615

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |                                    |  |
|------------------------------|--------------------------------------|------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/049,558 | <b>Applicant(s)</b><br>MENZ ET AL. |  |
|                              | <b>Examiner</b><br>Micah-Paul Young  | <b>Art Unit</b><br>1615            |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 18-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/14/02</u> . | 6) <input type="checkbox"/> Other: ____.  |

## DETAILED ACTION

**Acknowledgment of Papers Received:** Information Disclosure Statement dated 02/14/02.

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 38-40, 42, 44, 46 and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Riess et al (USPN 5,573,757 hereafter '757). The claims are drawn to a composition comprising a gel comprising fluorinated surfactant, water and a nonpolar component.

The '757 patent discloses a highly fluorinated gel composition comprising fluorinated hydrocarbon, an aqueous phase, and a fluorinated surfactant (col. 2, lin. 28 – 43). The composition is the form of a gel, where the fluorocarbon components are perfluorocarbon compounds (col. 2, lin. 44-56). The fluorocarbon concentration is higher than 60% and is as high as 99.7% (col. 4, lin. 11-17). The formulation is silent to the ophthalmic use of the formulation yet it is the position of the examiner that such a limitation represents a future intended use and does not impart patentability on a composition claim. See also *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997). With this in mind these disclosures render the claims anticipated.

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***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 18-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Riess et al (USPN 5,573,757 hereafter '757) and Meadows (USPN 5,480,914 hereafter '914). The claims are drawn to a method of treating the eye of a mammal comprising the external application of a composition comprising a gel comprising fluorinated surfactant, water and a nonpolar component. Claims 38 are drawn to the composition used in the method of claims 18-37.

6. As discussed above the '757 patent discloses the composition of the claims. The composition of the '757 patent comprises fluorinated surfactants, water and fluorocarbon components (col. 2, lin. 28-43). The reference is silent to ophthalmic applications yet suggests that the formulation forms a thin protective film upon application. The film is protects the area

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against contamination and dust, yet allows the passage of oxygen to the area (col. 7, lin. 16-35).

Due to the highly fluorinated nature of the composition, it serves as a lubricant (*Ibid.*). These properties are essential to any ophthalmic formulation, since the eye requires large amounts of oxygen, and lubrication in order to avoid irritation and possible infection, as seen in the '914 patent (col. 7, lin. 36-61)

The reference further differs from the claims in that it is silent to the surface tension of the composition, as well as the refraction index. However the reference discloses the general condition of a fluorocarbon composition, which protects the application situs, lubricates the surface and applies as a thin coating. The components are identical and in similar concentrations. Burden is shifted to applicant to provide a patentable distinction between the reference and the claims. The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

7. With these things in mind a skilled artisan would have been motivated follow the suggestions of the '757 patent along with the knowledge in the art as seen by the '914 patent to apply the composition of '757 to the eye externally in order to provide a protective, lubricating film capable of protecting the eye. It would have been obvious to a skilled artisan to follow

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these suggestions and teachings with an expected result of a lubricating fluorocarbon composition useful for protecting the eye from contamination while allowing oxygen to pass through to the eye, hydrating the eye.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
MP Young

Micah-Paul Young  
Examiner  
Art Unit 1615

THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
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